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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27387	7590	06/28/2005		
NORRIS, MCLAUGHLIN & MARCUS, P.A. 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022			EXAMINER COLLINS, CYNTHIA E	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/831,083

Applicant(s)

HEIM, UTE

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 Oct 2004, 12 Jan 2005, 30 Mar 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Amendments filed October 29, 2004, January 12, 2005 and March 30, 2005 have been entered.

Claims 14-18 are cancelled.

Claims 1-9, 11-13, 20 and 23 are currently amended.

Claims 1-13 and 19-23 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-2 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The limitation "an isolated polynucleotide comprising at least 88% identity with the polynucleotide sequence of SEQ ID NO:1" recited in currently amended claim 1 does not find support in the specification as originally filed and thus constitutes new matter. The limitation "a DNA sequence according to SEQ ID NO. 1 comprising at least 88% identity with the DNA sequence of SEQ ID NO:1" recited in currently amended claim 13 also does not find support in the specification as originally filed and thus constitutes new matter.

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Claims 1-2, 13 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims as currently amended are directed to promoter sequences having at least 88% identity with the DNA sequence of SEQ ID NO:1.

SEQ 1 is disclosed in the sequence listing as a 1783 bp promoter polynucleotide obtained from *Vicia faba*. The specification does not describe the sequences of other polynucleotides that have at least 88% identity with the DNA sequence of SEQ ID NO:1 and that function as seed-specific promoters.

The Federal Circuit has recently clarified the application of the written description requirement to polynucleotides. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses undisclosed and uncharacterized polynucleotide sequences that have at least 88% identity with the DNA

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sequence of SEQ ID NO:1 and that function as seed-specific promoters, nor the structural features unique to the genus.

Claims 11-13 and 20-22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed July 26, 2004

Applicant's arguments filed October 29, 2004 have been fully considered but they are not persuasive.

Applicant maintains that the plasmids in question are isolated by methods sufficiently described in the specification, particularly at pages 6-8, so as to allow persons in the art to practice the claimed invention without undue experimentation. Applicant also maintains that a reasonable basis for questioning the enabled of the rejected claims is not established. (reply pages 6-8)

The Examiner maintains that the specification does not disclose a repeatable process to obtain the exact same vector in each occurrence. While the teaching in the specification and the knowledge of one skilled in the art may enable one skilled in the art to make vectors that are similar and/or identical to pSBPROCS, pPTVSBPRGUS, pSBPR15 and pSBPOCS, the disclosed cloning techniques by their nature do not produce the exact same vector, identical in polynucleotide sequence, in each cloning occurrence. Accordingly the rejection is maintained.

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Claims 1-10, 19 and 23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated promoter DNA fragment obtained from *Vicia faba* that is a 1539 bp sequence 5' to the ATG of the *Vicia faba* sucrose binding protein (SBP) gene VfSBP20 in plasmid SBPR7, an isolated promoter the DNA fragment obtained from *Vicia faba* that is a 1750 bp of sequence 5' to the ATG of the *Vicia faba* sucrose binding protein (SBP) gene VfSBP20 in plasmid SBPR15, and an isolated polynucleotide of SEQ ID NO:1, as well as expression cassette, plasmids, plant cells and plants comprising said isolated promoter DNA fragments, does not reasonably provide enablement for isolated polynucleotides having at least 88% identity with SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed July 26, 2004 and for the reasons set forth below.

Applicant's arguments filed October 29, 2004 have been fully considered but they are not persuasive.

Applicant maintains that the thrust of the outstanding rejection is that SEQ ID NO:1 is a sequence of 1783 bp, whereas the largest promoter fragment disclosed in 1750 bp. In this regard Applicant points to the specification at page 7 as disclosing that the 1539 and 1750 bp clones are to the 5'side of the ATG of the SBP gene, and Applicant further points out that base pairs 1751 to 1753 of SEQ ID NO:1 form the SBP ATG translation initiation codon, such that the promoter portion of SEQ ID NO:1 ends at base pair 1750, the same length and sequence of the largest disclosed promoter fragment.

(reply pages 8-9)

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The Examiner acknowledges Applicant's disclosure and explanation regarding the promoter portion of SEQ ID NO:1 and the scope of enablement rejection has been adjusted accordingly. The rejection is maintained, however, because polynucleotide sequences that have at least 88% identity with the DNA sequence of SEQ ID NO:1 and that function as seed-specific promoters are not enabled.

The full scope of the claimed invention is not enabled because it is unpredictable whether variants of SEQ ID NO:1 would function as a promoter, or as a seed-specific promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the polynucleotide, which nucleotides and motifs may not be present in variants of SEQ ID NO:1.

Variants of SEQ ID NO:1 may lack key nucleotides required for basal promoter function. See, for example, Kim Y et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (*nos*) promoter activity. *Plant Mol Biol.* 1994 Jan;24(1):105-17), who teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

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Variants of SEQ ID NO:1 may also lack key nucleotide motifs required for tissue-specific promoter function. See, for example, de Pater S et al. (A 22-bp fragment of the pea lectin promoter containing essential TGAC-like motifs confers seed-specific gene expression. *Plant Cell*. 1993 Aug;5(8):877-86), who teach that a 22 bp region located from nucleotide -56 to nucleotide -35 of the pea lectin promoter sequence contains three overlapping TGAC-like motifs that function to confer seed-specific gene expression to the promoter (page 877 abstract; page 879 Figure 2).

In the instant case Applicant has not provided guidance with respect to the identity and location of key nucleotides and regulatory regions required for basal or tissue-specific promoter function, in SEQ ID NO:1 or in its variants. Absent such guidance it would require undue experimentation for one skilled in the art to use variants of SEQ ID NO:1, as one skilled in the art would have to isolated from undisclosed sources and/or synthesize variant nucleic acid sequences having at least 88% identity with SEQ ID NO:1, and then test each sequence for basal and seed-specific promoter function in order to discriminate between operative and nonoperative polynucleotides encompassed by the claims.

Claim 1, and claim 2 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "suitable for expressing arbitrary genes in plant seeds". It is unclear whether the claim in fact requires actual expression of arbitrary genes in plant seeds by the claimed isolated polynucleotide.



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Claim 3, and claims 4-13 and 19-23 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite in the recitation of "the plant seed". There is insufficient antecedent basis for this limitation in the claim.

Claim 3, and claims 4-13 and 19-23 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite in the recitation of "capable of being expressed". It is unclear whether the claim in fact requires that the gene be expressed.

Claim 13, and claims 20-22 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the office action mailed July 26, 2004

Applicant's arguments filed October 29, 2004 have been fully considered but they are not persuasive.

Claim 13 was rejected for reciting the limitation "the expression cassette containing a DNA sequence for over-expression of genes in plant seeds" in part (e), as there is insufficient antecedent basis for this limitation in the claim. Claim 13 was also rejected for reciting the limitation "the expression cassette containing an gene under the

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control of the promoter according to claim 1” in part (f), as there is insufficient antecedent basis for this limitation in the claim.

Applicant maintains that the amendment to the claim addresses the rejections, and that antecedent for “the expression cassette” appears in the preamble of claim 13 (reply page 5).

The rejection is maintained because the recitation of “the expression cassette according to claim 3 comprising a DNA sequence for seed-specific gene expression” in the preamble of claim 13 does not provide antecedent for the recitation of “the expression cassette containing a DNA sequence for over-expression of genes in plant seeds” recited in part (d) of the body of claim 13, as the claim preamble is not interpreted as limiting the method recited in the claim body. Further, an expression cassette according to claim 3 comprising a DNA sequence for seed-specific gene expression differs from an expression cassette containing a DNA sequence for over-expression of genes in plant seeds, as the former directs seed-specific gene expression, whereas the latter is for over-expression of genes in plant seeds. The rejection is also maintained because the amendment to the claim does not provide antecedent for “the expression cassette containing an gene under the control of the promoter according to claim 1” in part (f).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Remarks*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Examiner  
Art Unit 1638

CC

*Cynthia Collins 6/21/05*